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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,544	03/29/2004	Claudio Bucolo	P03314	3426

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EXAMINER	
HENRY, MICHAEL C	
ART UNIT	PAPER NUMBER
1623	
MAIL DATE	DELIVERY MODE
03/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/812,544	BUCOLO ET AL.	
	Examiner	Art Unit	
	MICHAEL C. HENRY	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/12/07*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6-12,40-53,69-71 and 73-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6-12,40-53,69-71 and 73-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 12/12/07.

The amendment filed 12/12/07 affects the application, 10/812,544 as follows:

1. The responsive to applicants' arguments is contained herein below. The rejection of the office action mailed 09/20/07 is maintained.

Claims 1-3, 6-12, 40-53, 69-71, 73-75 are pending in the application

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 6-12, 40-53, 69-71, 73-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al. (JP 62122671 A2, (English Translation)).

In claim 1, applicant claims a viscoelastic composition comprising water, 0.6%w/v to 4%w/v of hyaluronic acid or a salt thereof and 0.1% w/v to 2%w/v of hydroxypropylmethylcellulose, wherein the viscoelastic composition has a pseudoplasticity index from 160 to 5000, and a weight ratio of hydroxypropylmethylcellulose to hyaluronic acid or a salt thereof from 0.1 to 1. Claims 2-3 are drawn to the composition of claim 1, wherein the hyaluronic acid and hydroxypropylmethylcellulose have specific average molecular weights ranges. Claims 6, 7 and 10 are drawn to the composition of claim 1, wherein the composition has specific osmolality, zero-shear viscosity and crossover frequency. Claims 8, 9, 11, 12, 69, 70, 71 are drawn to the

composition of claim 1, wherein the composition has specific viscosity, chemical scavenger including citrate and sorbitol, pH of about 5-8 and specific buffer.

Yamamoto et al. disclose a viscoelastic composition comprising water, 1.0-2.0 w/v% of hyaluronic acid or a salt thereof and 1.0-2.0 w/v% of hydroxypropylmethylcellulose, and a ratio of hydroxypropylmethylcellulose to hyaluronic acid or a salt thereof of 1 (see page 3, 3rd paragraph). Furthermore, Yamamoto et al. disclose a composition that has the same viscosity (1000-10000 cps (centipoise)), chemical scavenger (citrate) and a pH (7.4) as applicant's composition (see page 3, 3rd paragraph and page 4, 4th paragraph). Also, Yamamoto et al.'s. disclose that sugars which includes xylitol and sorbitol can be used (see page 3, 2nd paragraph). In addition, Yamamoto et al. disclose that their composition can be used as a highly viscous liquid that is extremely effective for prevention of corneal disorders during intraocular surgery (see page 5, last paragraph).

The difference between applicant's claimed composition and the composition of Yamamoto et al. is that Yamamoto et al. do not determine the pseudoplasticity index of the composition.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to prepare the composition suggested by Yamamoto et al. and to determine the physical characteristics such as the pseudoplasticity index of said composition in order to use it as a highly viscous liquid to treat or prevent corneal disorders during intraocular surgery.

One having ordinary skill in the art would have been motivated, to prepare the composition suggested by Yamamoto et al. and to determine the physical characteristics such as the pseudoplasticity index of said composition in order to use it as a highly viscous liquid to treat or

prevent corneal disorders during intraocular surgery. It should be noted that the use of specific ratios of % w/v, amounts and molecular weights of the components in the composition depend on factors such as the severity and type of the corneal disorders treated.

Claim 40 is drawn to a package for a viscoelastic compoisition, the package comprising a syringe containing a viscoelastic composition 0.6%w/v to 4%w/v of hyaluronic acid or a salt thereof and 0.1% w/v to 2%w/v of hydroxypropylmethylcellulose, wherein the viscoelastic composition has a pseudoplasticity index from 160 to 5000, and a weight ratio of hydroxypropylmethylcellulose to hyaluronic acid or a salt thereof from 0.1 to 1. Claims 41 and 42 are drawn to the specific properties of the package comprising the composition and the intended use of the composition. Claims 43-44 are drawn to the composition of claim 40, wherein the hyaluronic acid and hydroxypropylmethylcellulose have specific average molecular weights ranges. Claims 47-49 and 51 are drawn to the composition of claim 40, wherein the composition has specific osmolality, zero-shear viscosity and crossover frequency. Claims 45 and 46 are drawn to the composition of claim 40, wherein the composition has specific %w/v of hyaluronic acid and hydroxypropylmethyl- cellulose. Claims 50, 52, 53, 70, 73-75 are drawn to the composition of claim 40, wherein the composition has specific viscosity and pH of about 6.5-7.5 and specific buffer.

Yamamoto et al. disclose a viscoelastic composition comprising water, 1.0-2.0 w/v% of hyaluronic acid or a salt thereof and 1.0-2.0 w/v% of hydroxypropylmethylcellulose, and a ratio of hydroxypropylmethylcellulose to hyaluronic acid or a salt thereof of 1 (see page 3, 3rd paragraph). Furthermore, Yamamoto et al. disclose a composition that has the same viscosity (1000-10000 cps (centipoise)), chemical scavenger (citrate) and a pH (7.4) as applicant's

composition (see page 3, 3rd paragraph and page 4, 4th paragraph). Also, Yamamoto et al.'s. disclose that sugars which includes xylitol and sorbitol can be used (see page 3, 2nd paragraph). Also,Yamamoto et al. disclose that buffers can be used (see page 3, 3rd paragraph). In addition, Yamamoto et al. disclose that their composition can be used as a highly viscous liquid that is extremely effective for prevention of corneal disorders during intraocular surgery (see page 5, last paragraph). It should be noted that the said package does not add to the patentability of the said composition. It should be noted that it is well settled that "intended use" of a composition or product, e.g., to force said composition through a stainless cannula, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

The difference between applicant's claimed composition and the composition of Yamamoto et al. is that Yamamoto et al. do not determine the pseudoplasticity index of the composition.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to prepare the composition suggested by Yamamoto et al. and to determine the physical characteristics such as the pseudoplasticity index of said composition in order to use it as a highly viscous liquid to treat or prevent corneal disorders during intraocular surgery.

One having ordinary skill in the art would have been motivated, to prepare the composition suggested by Yamamoto et al. and to determine the physical characteristics such as the pseudoplasticity index of said composition in order to use it as a highly viscous liquid to treat or prevent corneal disorders during intraocular surgery. It should be noted that the use of specific ratios of % w/v, amounts and molecular weights of the components in the composition depend on factors such as the severity and type of the corneal disorders treated.

Response to Arguments

Applicant's arguments with respect to claims 1-3, 6-12, 40-53, 69-71, 73-75 have been considered but are not found convincing.

The applicant argues that Applicants submit that there is no description in JP'671 of having weight ratio of HPMC to HA from 0.1 to 1.0. The rejection fails to recognize the importance of the weight ratio, and how this weight ratio is required if the claimed composition is to possess the recited pseudoplasticity index. There is no specific description in JP'671 of such a mixture having the claimed weight ratio, and consequently, the claimed pseudoplasticity index. More importantly, there is no suggestion in JP'671 to prepare such a mixture having any one of the viscoelastic properties recited in the clams. However, Yamamoto et al. disclose that for their viscoelastic composition, HPMC can have concentration of 1.0-2.0 w/v% and HA a concentration of 1.0-2.0 w/v%. This implies that when the concentration of the HPMC equals the concentration of HA (e.g., 1.0 w/v %) then the weight ratio of HPMC to HA equal 1.0. It should be noted that w/v% is equal to g/100 ml of solution. As example, for a 100 ml solution containing 1.0 w/v % of HPMC and 1.0 w/v % HA, the weight of HPMC in said solution = the weight of HA in said solution = 1g, and that equates to the weight ratio of HPMC to HA = 1.0 (which is the same weight ratio claimed by applicant). It should be noted that this weight ratio is a weight ratio which applicant argues that is required if the claimed composition is to possess the recited pseudoplasticity index.

The applicant argues that there is no teaching or suggestion in the JP'671 application of any one viscoelastic composition having any one of these recited properties. However, Yamamoto et al. disclose a viscoelastic composition comprising water, 1.0-2.0 w/v% of

hyaluronic acid or a salt thereof and 1.0-2.0 w/v% of hydroxypropylmethylcellulose, and a ratio of hydroxypropylmethylcellulose to hyaluronic acid or a salt thereof of 1 (see page 3, 3rd paragraph). It should be noted that the characteristic pertaining to the pseudoplasticity index of the composition is also addressed above (see the above rejection). Furthermore, Yamamoto et al. disclose that for their viscoelastic composition, HPMC can have concentration of 1.0-2.0 w/v% and HA a concentration of 1.0-2.0 w/v%. This implies that when the concentration of the HPMC equals the concentration of HA (e.g., 1.0 w/v %) then the weight ratio of HPMC to HA equal 1.0. It should be noted that w/v% is equal to g/100 ml of solution. As example, for a 100 ml solution containing 1.0 w/v % of HPMC and 1.0 w/v % HA, the weight of HPMC in said solution = the weight of HA in said solution = 1g, and that equates to the weight ratio of HPMC to HA = 1.0 (which is the same weight ratio claimed by applicant). It should be noted that this weight ratio is a weight ratio which applicant argues that is required if the claimed composition is to possess the recited pseudoplasticity index.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

/Shaojia Anna Jiang, Ph.D./
Supervisory Patent Examiner, Art Unit 1623
March 12, 2008.